UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: December 26, 2002

SUBJECT: Secondary Review of Contractor's (DynCorp 1 & ET) Efficacy Review-w for Sani-Wipe, EPA Reg. No. 9480-7;
DP Barcode: D284771
Case No. 065184

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APPLICANT: Nice-Pak Products, Inc.
Orangeburg, New York 10962

Formulation From Label:

Active Ingredient(s)	% by wt
n-alkyl(C_{12}67%,C_{14}25%,C7%,C_8,C_{10},C_{18},1%,Dimethyl Benzyl Ammonium Chloride	0.0175%
Isopropyl Alcohol	504800%
Inert Ingredients(s)	94.5025%
Total	100.000%

I. BACKGROUND

The product, Sani-Wipe (EPA Reg. No. 9480-7), is an EPA-approved food-contact surface sanitizer for use on hard, non-porous surfaces. The applicant requested an amendment to the registration of this product to add claims for use of the product as a sanitizing wipe on hard, non-porous, food-contact surfaces in food service settings, restaurants, food processing areas, and households.

The applicant is submitting additional data in response to EPA's July 3, 2002 comments on the previously submitted proposed label. EPA provided instructions to the applicant regarding the submission of efficacy data for use of the product as a sanitizer on food-contact surfaces (which are distinct from instructions provided for non-food-contact surfaces). As requested by EPA, the applicant submitted data for use of the product as a food-contact surface sanitizer, specifically the final report for the already completed food-contact data on glass surfaces using *Staphylococcus aureus* and *Escherichia coli*. The study was conducted at Mycoscience Labs, Inc. located at 25 Village Hill Road, Willington, Connecticut 06279.

This data package contained one study (MRID No. 457295-01), a Statement of No Data Confidentiality Claim, and the last accepted label (dated July 3, 2002). The MRID included data involving two types of carriers. Only the data for studies conducted on glass surfaces was reviewed. The data package did not include a proposed label.

II. USE DIRECTIONS

The product is designed to be used for sanitizing hard, non-porous, food-contact surfaces such as countertops, drain boards, and non-wood cutting boards. Directions on the last accepted label (dated July 3, 2002) provided the following information regarding preparation and use of the product as a food-contact surface sanitizer: Pre-clean if surface is visibly soiled. Wipe surface so that it remains visibly wet for 30 seconds. Let air dry.

The directions also provided the following instructions: Do not use to sanitize eating utensils, glassware, cookware, and food processing equipment. Do not apply directly to any type of human food. Do not use for cleaning or sanitizing human skin. Do not use as a diaper wipe or for personal cleansing.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Non-Residual Sanitization of Hard Inanimate Food-Contact Surfaces Using Pre-Saturated, Single Use Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in sanitizing hard surfaces. The standard test methods available (e.g., AOAC Germicidal Spray Products Test, AOAC Germicidal and Detergent Sanitizing Action Method), if followed exactly,

would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the AOAC Germicidal Spray Products Test against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11299) on two carrier surfaces: (1) stainless steel or glass, and (2) plastic with a rough surface (i.e., plastic cutting board). Inoculated carriers should be dried for 40 minutes at 30-37°C. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a 30-second holding time. Liquid expressed from the used towelette should also be subcultured. Tests are to be conducted in triplicate. Three product samples, representing three different batches, one of which is at least 60 days old, must be tested. Starting inocula must provide 75-125 x 10^6 CFU/mL on the parallel control surface. Additional organisms may be tested, using two batches of product. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. Subcultures of the liquid expressed from the used towelettes should be negative for growth. The study report must provide systematic and complete descriptions of the tests employed and the results obtained. Label directions must state that the towelette must be visibly wet (saturated) before use, and the treated surface must be visibly wet after use. Additionally, the label must identify the recommended maximum surface area to be treated, which must be reflective of the surface area tested in the study. The above Agency standards are presented in the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes. This guidance does not address products for use on utensils, glasses, food containers, dishes, and food processing equipment.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 457295-01 "Nice-Pak Products, Inc. Efficacy Study of Single Use Impregnated Towelettes, For Use as a Sanitizer for Food-Contact Surfaces" for Sani-Wipe, by Richard E. Arsenault. Study completion date – July 30, 2002.

This study was conducted against *Stapylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229) in the presence of a 5% organic soil load (bovine serum). Four lots of the product, Large Sani-Wipe, were tested (Lot Nos. L-1297-A, L-1297-B, L-2028-A, and L-2086-A). Two product lots (Lot Nos. L-1297-A, L-1297-B) were at least 60 days old at the time of testing. Eight 6 x 12 inch sections of glass surface (a total area of 4 ft^2) were inoculated with 0.125 mL of the culture suspension (for a total of 1 mL per eight 6 x 12 inch sections). The inoculum was spread uniformly over each surface. The glass surfaces were dried at room temperature for 30 minutes. One wipe was used to wipe 4 ft^2 of inoculated surface area. The wiped surface was allowed to sit for 30 seconds. The glass surface was transferred to a sterile stomacher bag containing 2,000 mL of sterile AOAC neutralizer solution. Thirty seconds after wiping the last surface, the wipe was transferred to 200 mL of sterile AOAC neutralizer blank solution; liquid was not directly expressed from the wipes. The 8 glass surfaces and wipe were then immediately sonicated for 10 minutes, followed by agitation by hand for 30 seconds. Carrier surfaces and wipes were assayed for surviving numbers of microorganisms using a membrane filtration technique. Appropriate aliquots (2, 20, 200 mL) of the carrier surface extracts and 2

and 20 mL of the wipe extracts were filtered through individual sterile bacterial retentive filters followed by a 50 mL rinse with AOAC neutralizing solution. The filters were transferred to the surface of Tryptone Glucose Extract Agar plates containing 25 mL AOAC stock neutralizer/L. The plates were incubated at 37±1 °C for a minimum of 48 hours and then enumerated. The studies were performed in triplicate. Controls included purity, sterility, neutralizer effectiveness, and parallel controls.

Note: The dimensions of the wipe are 8 x 10 inches.

Note: Lot No. L-1297-A was re-tested against *Staphylococcus aureus* per the applicant's request due to the relatively high challenge inoculum level and subsequent failure on 2 of the replicates.

Note: Lot No. L-2086-A was re-tested against *Escherichia coli* because the parallel control count was under the minimum requirement of 75 x 10^6 CFU/surface.

Note: The MRID identified one deviation from GLP protocol. An additional lot of product (i.e., Lot No. L-2086-A) was incorporated into the study, per the applicant's request, to replace Lot No. L-1297-A (which had low levels of the active ingredient).

V. RESULTS

MRID Number	Organism	Lot	Reported Parallel Control Count* (CFU)	Parallel Control Count, Carrier Surface (CFU)	Reported % Reduction
457295-01	*Staphylococcus aureus*	L-1297-A (initial)	8.82 x 10^8	2.42 x 10^8	99.9981 99.999 99.9983
		L-1297-A (retest)	2.94 x 10^8	7.2 x 10^7	99.999 99.997 99.996
		L-1297-B	2.36 x 10^8	4.0 x 10^7	99.999 99.999 99.999
		L-2028-A	8.8 x 10^8	1.4 x 10^8	99.999 99.999 99.999
		L-2086-A	3.3 x 10^8	5.2 x 10^7	99.9959 99.999 99.999

MRID Number	Organism	Lot	Reported Parallel Control Count* (CFU)	Parallel Control Count, Carrier Surface (CFU)	Reported % Reduction
457295-01	*Escherichia coli*	L-1297-B	9.5×10^7	1.1×10^7	99.999 99.999 99.999
		L-2028-A	1.14×10^8	1.22×10^7	99.999 99.999 99.999
		L-2086-A (initial)	3.26×10^7	6.6×10^6	99.999 99.999 99.998
		L-2086-A (retest)	2.66×10^8	6.4×10^7	99.999 99.999 99.999

* The Reported Parallel Control Count is actually the sum of the parallel control count (carrier surface) and the parallel control count (wipe).

VI. CONCLUSION

1. The submitted efficacy data (MRID No. 457295-01) do not support the use of the product, Sani-Wipe, as a food-contact surface sanitizer when tested against *Staphylococcus aureus* and *Escherchia coli* in the presence of a 5% organic soil load (bovine serum) on hard, non-porous glass surfaces for a contact time of 30 seconds. Data provided in the MRID included "CFU Recovered" (both carrier surface and wipe), "Total CFU Recovered", and "Percent Reduction", for the three replicates and the parallel control. Note that the "Total CFU Recovered" values are the sum of CFU recovered from the carrier surface (as is appropriate) plus the CFU recovered from the used wipe (which the Agency guidance does not require). The CFU should have been based only on the surface and not the surface and wipe together. As well, the surface count which should have been the initial count was too low.

2. Also, the 10 minute sonication time for the towelette is too long, and should be reduced to no more than 5 minutes in an effort not to damage cells.

Organism	Lot	Parallel Control Count, Carrier Surface (CFU)	Comments on Parallel Control Count, Carrier Surface
Staphylococcus aureus	L-1297-A (initial)	242 x 10^6	too high
Staphylococcus aureus	L-1297-A (retest)	72 x 10^6	too low
Staphylococcus aureus	L-1297-B	40 x 10^6	too low
Staphylococcus aureus	L-2028-A (initial)	140 x 10^6	too high
Staphylococcus aureus	L-2086-A (retest)	52 x 10^6	too low
Escherichia coli	L-1297-B	11 x 10^6	too low
Escherichia coli	L-2028-A	12.2 x 10^6	too low
Escherichia coli	L-2086-A (initial)	6.6 x 10^6	too low
Escherichia coli	L-2086-A (retest)	64 x 10^6	too low

VII. RECOMMENDATIONS

1. The label claims (as supported by MRID No. 457295-01) are not acceptable regarding the use of the product, Sani-Wipe, as a food-contact surface sanitizer against *Staphylococcus aureus* and *Escherichia coli* in the presence of a 5% organic soil load (bovine serum) on hard, non-porous surfaces for a contact time of 30 seconds. The product lots tested against *Escherichia coli* and *Staphylococcus aureus* did not provide valid results, due to an insufficient parallel control count (carrier surface).

2. Remove all label claims to *Listeria monocytogenes* (ATCC 19115), and *Shigella boydii* (ATCC 9207), as these claims are not yet supported. EPA understands that these data are expected by February 1, 2003.

3. Sonication time for the towelette should be reduced to no more than 5 minutes.